IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9167

Bartle, J. November 21, 2013

The Estate of Iris R. Martin ("Estate"), a representative claimant under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether the Estate has demonstrated a reasonable medical basis to support its claim for Matrix Compensation Benefits ("Matrix Benefits") and, if so, whether the Estate met

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Donald H. Martin, the spouse of Iris R. Martin ("Ms. Martin"), also has submitted a derivative claim for benefits.

its burden of proving that its claim was not based, in whole or in part, on any intentional material misrepresentations of fact.[3]

To seek Matrix Benefits, a representative claimant[4] must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician, who must answer a series of questions concerning the Diet Drug Recipient's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, if the representative claimant is represented by an attorney, the attorney must complete Part III.

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3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify Diet Drug Recipients for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to the Diet Drug Recipient's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to representative claimants where the Diet Drug Recipients were diagnosed with serious VHD, they took the drugs for 61 days or longer, and they did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to representative claimants where the Diet Drug Recipients were registered as having only mild mitral regurgitation by the close of the Screening Period, they took the drugs for 60 days or less, or they were diagnosed with conditions that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Under the Settlement Agreement, representative claimants include estates, administrators or other legal representatives, heirs, or beneficiaries. See Settlement Agreement § II.B.

In May, 2003, Ms. Martin submitted a completed Green Form to the Trust signed by her attesting physician, S. Ronald Kline, M.D. Based on an echocardiogram dated July 27, 2002, Dr. Kline attested in Part II of the Green Form that Ms. Martin suffered from moderate mitral regurgitation and an abnormal left atrial dimension.[5] Based on such findings, Ms. Martin would be entitled to Matrix A-1, Level II benefits in the amount of $212,106.[6]

In the report of Ms. Martin's echocardiogram, Dr. Kline observed that Ms. Martin had "[m]oderate mitral valve regurgitation" of 30%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Kline also measured Ms. Martin's left atrial antero-posterior dimension as 5.1 cm and her left atrial supero-inferior dimension as 6.2 cm. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial antero-posterior systolic dimension greater than

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5. Dr. Kline also attested that Ms. Martin suffered from New York Heart Association Functional Class III symptoms. This condition is not at issue in this claim.

6. Under the Settlement Agreement, an eligible claimant or representative claimant is entitled to Level II benefits for damage to the mitral valve if the Diet Drug Recipient is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left atrial dimension is one of the complicating factors necessary for a Level II claim.

4.0 cm in the parasternal long-axis view or a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view. See id. at § IV.B.2.c.(2)(b)ii).

In January, 2004, the Trust forwarded the claim for review by Craig M. Oliner, M.D., one of its auditing cardiologists. In audit, Dr. Oliner determined that, although "the color Doppler [was] slightly overgained" and "the traced RJA's [were] of questionable accuracy, drawn from freeze frames without real time [mitral regurgitation] data," there was a reasonable medical basis for Dr. Kline's findings that Ms. Martin had moderate mitral regurgitation and an abnormal left atrial dimension.[7]

Based on Dr. Oliner's findings, the Trust issued a post-audit determination awarding Ms. Martin Matrix Benefits. Before the Trust paid Ms. Martin's claim, we imposed a stay on the processing of claims pending implementation of the Seventh Amendment to the Settlement Agreement. See Pretrial Order ("PTO") No. 3511 (May 10, 2004). Prior to the entry of the stay, the Trust identified 968 Matrix claims that had passed audit as payable, which were designated as "Pre-Stay Payable Post-Audit Determination Letter ('PADL') Claims." Pursuant to Paragraph 5

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7. Dr. Oliner also determined that there was no reasonable medical basis for Dr. Kline's representation that Ms. Martin did not have mitral annular calcification. Under the Settlement Agreement, the presence of mitral annular calcification requires the payment of reduced Matrix Benefits for a claim based on damage to the mitral valve. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d). Given our disposition, we need not decide this issue.

of PTO No. 3883, the Trust was ordered to separate the Pre-Stay Payable PADL Claims into three categories. Of the 968 Pre-Stay Payable PADL Claims, the Trust alleged that 580 claims, including Ms. Martin's, contained intentional material misrepresentations of fact. These 580 claims are commonly referred to as "5(a) claims." See PTO No. 3883, at ¶ 5 (Aug. 26, 2004).

Following the end of the stay, we ordered the Trust to review the 580 claims designated as 5(a) claims and issue new post-audit determinations, which claimants could contest. See PTO No. 5625 (Aug. 24, 2005). Prior to the Trust's review of Ms. Martin's claim, this court approved, on November 22, 2006, Court Approved Procedure ("CAP") No. 13, which provided 5(a) claimants with the option either to submit their claims to a binding medical review by a participating physician or to opt-out of CAP No. 13. See PTO No. 6707 (Nov. 22, 2006). The Estate elected to opt-out of CAP No. 13.[8]

The Trust therefore undertook to determine whether there were any intentional material misrepresentations of fact made in connection with the Estate's claim. As part of this review, the Trust engaged Joseph Kisslo, M.D., to review the integrity of the echocardiogram system used during the performance of echocardiographic studies and the resulting interpretations submitted in support of the Estate's claim. As

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8. Ms. Martin passed away on December 29, 2005, and the Estate was substituted as the proper party. Iris P. Rodriguez was named executrix of Ms. Martin's estate.

stated in his March 8, 2007 declaration, Dr. Kisslo determined, in pertinent part, that:

> In Ms. Martin's study, the use of high color gain, excessive depth, a decreased Nyquist setting, high image gain, and color pixels dominant over anatomy, the selection and planimetry of backflow, and the overmeasurement of the mitral "jet" are the result of deliberate choices and conduct engaged in by the sonographer performing this study and at a minimum, acquiesced in by the Attesting Physician. Each of these manipulations exaggerated or created the appearance of regurgitation and jet duration. There is no responsible physiologic or hemodynamic construct under which this echocardiogram can be assessed as demonstrating moderate mitral regurgitation. Ms. Martin has no mitral regurgitation--not moderate mitral regurgitation as claimed by the Attesting Physician. There is no reasonable medical basis for a finding of moderate mitral regurgitation based on this study.

Thus, notwithstanding Dr. Oliner's findings at audit, the Trust rescinded its prior post-audit determination and issued a new post-audit determination denying the Estate's claim based on its conclusion that there was substantial evidence of intentional material misrepresentations of fact in connection with the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), the Estate contested this adverse determination.[9] In contest, the Estate argued that the

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9. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit (continued...)

Trust failed to provide substantial evidence of intentional material misrepresentations of fact in connection with its claim, and that, even if the Trust provided such evidence, it was insufficient to outweigh the contrary evidence that no intentional material misrepresentation occurred. In support of this position, the Estate contended that deference should be shown to the opinions of the attesting physician and the auditing cardiologist, both of whom determined that there was a reasonable medical basis for the claim. The Estate also noted that Ms. Martin had submitted a second study conducted on a "more sophisticated machine" than the echocardiogram on which the claim is based. The second study was prepared due to concerns regarding the "low quality condition" of the machine used to conduct the earlier echocardiogram. The second echocardiogram "suggest[ed] that the claimant did not have a matrix level condition." The Estate argued that while it may have a "weak claim," the open disclosure of this conflicting medical opinion undermines any contention that Ms. Martin intended to mislead the Trust regarding the potential merits of the claim.

The Trust then issued a final post-audit determination, again denying the Estate's claim. The Trust argued that the Estate misinterpreted the legal obligations under Audit Rules and that "[t]he burden of proof remains on the Claimant throughout these proceedings" to establish that there is a reasonable

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9. (...continued)
Rules contained in PTO No. 2807 apply to the Estate's claim.

medical basis in support of its claim - not on the Trust to prove that intentional material misrepresentations of fact exist. The Trust also asserted that the Estate's contest did not satisfy this burden. First, the Trust pointed to the Estate's concession that the echocardiogram on which the claim was based was "poorly performed" and that the second, higher quality echocardiogram reflected that Ms. Martin did not suffer from conditions qualifying for Level II benefits. Second, the Trust contended that the auditing cardiologist's inability to detect all of the misrepresentations in connection with Ms. Martin's echocardiogram did not satisfy the Estate's burden because Dr. Oliner was neither trained to detect the types of "manipulations employed by Coastal Cardiac [Imaging]" nor familiar with its patterns of activity as described in Dr. Kisslo's report. Third, the Trust stated that while the Estate raised numerous contentions and criticisms pertaining to Dr. Kisslo's declaration, the Estate did not identify any alleged errors in Dr. Kisslo's findings.

The Estate disputed the Trust's final determination and requested that the claim proceed through the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the Estate's claim should be paid. On August 2, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7348 (Aug. 2, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The Estate then served a response upon the Special Master. The Trust submitted a reply on October 24, 2007. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[10] to review claims after the Trust and the Estate have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and the Estate and prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether the Estate has met its burden of proving that there is a reasonable medical basis for its claim. Where the Trust's post-audit determination finds intentional material misrepresentations of fact, the representative claimant has the burden of proving that all representations of material fact in connection with the claim are true. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical

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10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

basis for the answers in the Green Form either because of an intentional material misrepresentation of fact or some other valid reason, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers with no intentional material misrepresentations of fact made in connection with the claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of its claim, the Estate incorporates the arguments it made at contest.[11] In addition, the Estate asserts that Dr. Kisslo's report should be stricken as violative of PTO No. 3883 to the extent it constitutes a re-audit of the claim.[12]

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11. The Estate also made repeated reference to a September 8, 2005 letter from Class Counsel to the Trust. In this letter, Class Counsel argued, among other things, that the Trust could not deny payment on any claim in which a post-audit determination letter had been sent unless it found that the claim was based on a fraudulent echocardiogram and that the Trust could not rely on the reports of Dr. Kisslo to determine whether a claim in which a post-audit determination letter had been sent was fraudulent. The issues raised in Class Counsel's letter also were the subject of a motion filed by Class Counsel and joined by a number of firms representing various Class Members. Class Counsel and all but one firm subsequently withdrew the motion after the adoption of certain Court Approved Procedures. We denied the motion of the remaining firm following briefing and argument. See PTO No. 6099 (Mar. 31, 2006).

12. The Estate also identifies a number of alleged procedural errors by the Trust in connection with its claim: (1) the Trust had a legal obligation to pay the Estate's claim prior to the May 10, 2004 stay; (2) the Trust should be precluded from

(continued...)

In response, the Trust argues that it did not re-audit the Estate's claim. According to the Trust, Dr. Kisslo was hired to assist the Trust in determining whether claims contained intentional material misrepresentations of fact.

The Technical Advisor, Dr. Vigilante, reviewed Ms. Martin's echocardiogram and concluded that it was not conducted in a manner consistent with medical standards. Specifically, Dr. Vigilante observed:

> The usual echocardiographic views were found on the study. However, the study was not conducted in a manner consistent with medical standards. There was high color gain with color artifact seen within the myocardium and outside of the heart. There was abnormal pixilation and stuttering of images related to persistence causing color artifact. The Nyquist limit was low in the apical views at 51 cm per second at a depth of 16.2 cm. In addition, the supposed RJAs planimetered by the sonographer were not representative of mitral regurgitation and were not seen in real time.

Despite these deficiencies, Dr. Vigilante noted that he was able to evaluate Ms. Martin's echocardiogram and determined that there was no reasonable medical basis for the attesting physician's finding that Ms. Martin had moderate mitral regurgitation. Dr. Vigilante explained in pertinent part that:

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12. (...continued)
contesting the Estate's claim because it failed to comply with the terms of PTO Nos. 3883 and 5625; and (3) the Trust should be precluded from contesting the Estate's claim because it failed to timely prosecute the claim. We reject the Estate's argument that its claim should be paid because the Trust did not comply with the procedural guidelines set forth in our various PTOs. None of the errors the Estate alleges, even if true, would change our disposition of this claim.

> [M]itral regurgitation was not seen in the parasternal long-axis view. A very small jet of apparent mitral regurgitation was seen visually in the apical four chamber but not apical two chamber view. I digitized the cardiac cycles in the apical four and two chamber views during color Doppler evaluation. In spite of increased artifact due to excessive color gain, persistence and a low Nyquist, I was able to evaluate the mitral regurgitant jet in several cardiac cycles in the mid portion of systole. In the apical four chamber view, it was a very small jet seen in the mid portion of systole within 1 cm of the mitral annulus. This study was diagnostic of trace mitral regurgitation in this view. There was no mitral regurgitation seen at all in the apical two chamber view. I determined that the LAA measured 19.4 cm2. The sonographer demonstrated a supposed RJA of 5.27 cm2 in the apical two chamber view and 5.89 cm2 in the apical four chamber view. These were freeze frame images that were not seen in real time and were not representative of mitral regurgitation. The sonographer did not demonstrate the planimetry of the LAA on this tape. However, the sonographer's LAA determination of 19.3 cm2 is similar to my LAA measurement of 19.4 cm2. It should be noted that there was no evidence of an RJA/LAA ratio coming close to 20%.[13]

After reviewing the entire Show Cause Record, we find the Estate has not established a reasonable medical basis for the attesting physician's finding that Ms. Martin had moderate mitral regurgitation. In reaching this determination, we are required to apply the standards delineated in the Settlement Agreement and Audit Rules. In the context of those two documents, we

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13. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, trace, trivial, or physiologic regurgitation is defined as a "[n]on-sustained jet immediately (within 1 cm) behind the annular plane of <+ 5% RJA/LAA."

previously have explained that conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See Mem. in Supp. of PTO No. 2640, at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Kisslo and Dr. Vigilante each found that Ms. Martin's sonographer improperly selected, traced, and measured a supposed regurgitant "jet." According to Dr. Vigilante, the supposed RJAs measured by the sonographer "were freeze frame images that were not seen in real time and were not representative of mitral regurgitation." In addition, Dr. Kisslo and Dr. Vigilante found that the echocardiogram of attestation was not conducted in a manner consistent with medical standards because, among other things, the echocardiogram settings included artifact resulting from excessive color gain and a low Nyquist to exaggerate the appearance of mitral regurgitation.

Notwithstanding these deficiencies, Dr. Kisslo and Dr. Vigilante determined that Ms. Martin's echocardiogram

demonstrated, at most, trace mitral regurgitation. In addition, Dr. Vigilante concluded, after a thorough review, that there was no reasonable medical basis for the attesting physician's opinion that Ms. Martin had moderate mitral regurgitation. Specifically, he explained that "there was no evidence of an RJA/LAA ratio coming close to 20%."

The Estate does not substantively challenge the specific findings of Dr. Kisslo or Dr. Vigilante regarding the manner in which Ms. Martin's echocardiogram was conducted.[14] In fact, the only substantive evidence upon which the Estate relies, a second study performed on a "more sophisticated" echocardiogram machine, undermines the echocardiogram of attestation and supports the conclusions of Dr. Kisslo and Dr. Vigilante that Ms. Martin did not have moderate mitral regurgitation.

We also reject the Estate's argument that the review of its claim by Dr. Kisslo constitutes an impermissible second audit. This argument ignores the plain language of the Audit Rules, which provides that the Trust must conduct a review separate from the auditing cardiologist with respect to whether there were any intentional material misrepresentations of fact in connection with a claim. Specifically, the Audit Rules state, in pertinent part, that:

> The Auditing Cardiologist shall review a Claim in accordance with these Rules to determine whether there was a reasonable

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14. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

> medical basis for each answer in Part II of the GREEN Form that differs from the Auditing Cardiologist's finding on that specific issue ("GREEN Form Question at Issue"). The Trust shall review a Claim to determine whether there were any intentional material misrepresentations made in connection with the Claim. The Trust may consider information from other Claims in Audit to determine the existence of facts or a pattern of misrepresentations implicating intentional misconduct by an attorney and/or physician that may warrant relief pursuant to Section VI.E.8 of the Settlement Agreement.

Audit Rule 5. Based on the findings of Dr. Kisslo, the Trust denied the Estate's claim, determining that the claim was based on one or more intentional material misrepresentations of fact.

The Estate disputed this determination and proceeded to the show cause process. We need not determine whether there was, in fact, any intentional material misrepresentation of fact in connection with the Estate's claim given our conclusion, based on our review of the entire record, that there is no reasonable medical basis for Dr. Kline's representation that Ms. Martin had moderate mitral regurgitation.[15]

For the foregoing reasons, we conclude that the Estate has not met its burden of proving that there is a reasonable medical basis for its claim. Therefore, we will affirm the

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15. As we previously have stated, "[s]imply because an undeserving claim has slipped through the cracks so far is no reason for this court to put its imprimatur on a procedure which may allow it to be paid." Mem. in Supp. of PTO No. 5625, at 6-7 (Aug. 24, 2005). In this same vein, we will not ignore the findings of other cardiologists simply because a claim has previously passed audit.

Trust's denial of the Estate's claim for Matrix Benefits and the related derivative claim submitted by Ms. Martin's spouse.